

This is an official

## CDC Health Advisory

### **Nosocomial *Burkholderia cepacia* pneumonia associated with contaminated alcohol-free mouthwash**

The Centers for Disease Control and Prevention (CDC) has been notified by several states of clusters of pneumonia and other infections caused by *Burkholderia cepacia*. These cases had exposure to alcohol-free mouthwash manufactured by Carrington Labs ( Irving , TX ) for Medline Industries ( Mundelein , IL ). Cultures performed by a hospital laboratory where the first cases were detected indicate that multiple lots of Medline alcohol-free mouthwash are intrinsically contaminated with *B. cepacia*. In August 2005, the Texas Department of State Health Services was notified of a cluster of nosocomial pneumonia involving three patients hospitalized at a Texas health-care facility.

All three patients were intubated and in the intensive care unit for their underlying illnesses when they developed signs of pneumonia and respiratory cultures grew *B. cepacia*. All three patients had received oral care using 4 oz. bottles of Medline alcohol-free mouthwash prior to illness onset. One patient has recovered and has been discharged. The second and third remain hospitalized, one with a poor prognosis. Molecular typing is pending. An additional two clusters (2 cases and 5 cases), both associated with prior use of Medline alcohol-free mouthwash, are currently being investigated in two Florida health-care facilities.

CDC is working with state health departments and the Food and Drug Administration to determine the magnitude of this outbreak. Carrington Labs analysis of in-house retain samples has confirmed contamination in multiple lots of the product in both 4 oz. and 2 oz. bottles leading to a recall of all alcohol-free mouthwash manufactured by Carrington Labs for Medline.

The suspect product bears a 7 or 8 digit lot number on the bottom of the bottle; suspect lot numbers include numbers 0503\*\*\* through 0508\*\*\* and 0503\*\*\*\* through 0508\*\*\*\* (asterisks represent any digit). The product is available in 2 oz. bottles as well as 4 oz. bottles and was distributed only to hospitals and long term care facilities. The product is not distributed for direct retail sale to the consumer. However, the 2 oz. bottles are packaged with other items, such as toothbrushes, toothpaste, etc. by Medline into a 'personal hygiene hospital admission kit' so some mouthwash may be in the possession of the consumer within a residential setting. Medline alcohol-free mouthwash with the above lot numbers should not be used. Individuals who are aware of cases of *B. cepacia* colonization or infection occurring during or shortly after exposure to these products should contact their health department and CDC at 1-800-893-0485.

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Categories of Health Alert messages:

**Health Alert**      conveys the highest level of importance; warrants immediate action or attention.

**Health Advisory**    provides important information for a specific incident or situation; may not require immediate action.

**Health Update**      provides updated information regarding an incident or situation; unlikely to require immediate action.